UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

AFSHIN ZARINEBAF, ZACHARY CHERNIK and JOAN MEYER, individually and on behalf of a class of similarly situated individuals, **PLAINTIFFS**, V. **CHAMPION PETFOODS USA, INC.** and **CHAMPION PETFOODS LP**, **DEFENDANTS**.	Case No. 1:18-CV-06951 Honorable Virginia M. Kendall **PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE PLAINTIFFS' EXPERT SEAN CALLAN**

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Plaintiffs oppose CPF's Motion to Exclude the Opinions and Testimony of Plaintiffs' Proffered Expert Sean Callan ("Motion" or "Mot.").[1] This Court should respectfully deny CPF's Motion in its entirety for the reasons set forth below.

I. INTRODUCTION

CPF's arguments for excluding Dr. Callan's opinions—that his testimony is irrelevant, baseless, and speculative and that his methodologies are flawed—lack merit and should be rejected. The criticisms in CPF's motion, at best, go only to the weight rather than the admissibility of Dr. Callan's opinions. Thus, it is up to a jury to decide the weight to give Dr. Callan's opinions.

Dr. Callan is a highly qualified professional whose testimony in this action meets the relevance and reliability requirements of Rule 702 of the Federal Rules of Evidence ("Rule 702") and *Daubert v. Merrell DOW Pharmaceuticals, Inc.*, 509 U.S. 579, 589 (1993). Based on his extensive experience and knowledge, and his review and analysis of relevant documentation and materials, Dr. Callan produced a report opining on: the presence of pentobarbital in certain raw materials used in creating the Dog Food;[2] the likely presence of pentobarbital at some level in the Dog Food; and the insufficiency of the random sampling performed by CPF to determine the risk of pentobarbital in the Dog Food. Dr. Callan's expert opinions are based on sufficient data and sound methodology, guided by his qualifications in the relevant fields, and are, as a result, helpful for a jury to understand the evidence and analysis related to the pentobarbital allegations in the present case. For these reasons and as discussed further below, CPF's Motion should be denied.

[1] "CPF" refers collectively to defendants Champion Petfoods USA, Inc. and Champion Petfoods LP.

[2] For purposes of this memorandum and Dr. Callan's report, the term "Dog Food" is limited to "Red Meat" diets of Acana Heritage Red Meats and Orijen Regional Red.

II. LEGAL STANDARD

"The admissibility of expert testimony is governed by [Rule] 702 and … *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993)." *Paine ex rel. Eilman v. Johnson*, No. 06-cv-3173, 2010 WL 785394, at *1 (N.D. Ill. Feb. 26, 2010) (citations and quotations omitted). "'If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.'" *Id.* (quoting Fed. R. Evid. 702.)

Importantly, "*Daubert* demands reliability, not perfection." *Williamson v. S.A. Gear Co., Inc.*, No. 15-cv-365, 2018 WL 1556281, at *4 (S.D. Ill. Mar. 29, 2018). "Questions related to the quality of the underlying data and the expert's conclusions are not a proper consideration." *Id.* Instead, "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert*, 509 U.S. at 596). The Court's role is to determine whether the expert is qualified, "whether the reasoning or methodology underlying the expert's testimony is reliable," and "whether the expert's proposed testimony will assist the trier of fact in understanding the evidence or to determine a factual issue." *Cage v. City of Chicago*, 979 F. Supp. 2d 787, 799 (N.D. Ill. 2013). District courts are given "wide latitude in performing [their] gatekeeping function and determining both how to measure the reliability of expert testimony and whether the testimony itself is reliable." *Lapsley v. Xtek, Inc.* 689 F.3d 802, (7th Cir. 2012) (quoting *Bielskis v. Louisville Ladder, Inc.*, 663 F.3d 887, 894 (7th Cir. 2011)); *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152-53 (1999). And "the key to the gate is not the ultimate correctness of the expert's conclusions. Instead, it is the soundness and care with which the expert arrived at [their] opinion: the inquiry must 'focus … solely on principles and methodology, not on the conclusions they generate.'"

Schultz v. Akzo Nobel Paints, LLC, 721 F.3d 426, 431 (7th Cir. 2013) (citing *Daubert*, 509 U.S. at 595)).

In determining the reliability of a proposed expert, "the role of the court is to determine whether the expert is qualified in the relevant field and to examine the methodology the expert has used in reaching [their] conclusions." *Smith v. Ford Motor Co.*, 215 F.3d 713, 718 (7th Cir. 2000). "[A] court should consider a proposed expert's full range of practical experience as well as academic or technical training when determining whether that expert is qualified to render an opinion in a given area." *Id*. "Expert testimony need only be relevant to evaluating a factual matter in the case. That testimony need not relate directly to the ultimate issue that is to be resolved by the trier of fact. *Id*. at 720. "The soundness of the factual underpinnings of the expert's analysis and the correctness of the expert's conclusions based on that analysis are factual matters to be determined by the trier of fact." *Id*. at 718.

III. ARGUMENT

A. Dr. Callan Is Qualified to Render His Opinions Regarding Pentobarbital Being "Likely Present" in CPF Dog Food at "Some Level," Which Is Based on Sufficient Data and Facts

CPF's efforts to discredit Dr. Callan's opinions regarding the likely presence of pentobarbital in CPF Dog Food as baseless, speculative, and irrelevant are unpersuasive and should be rejected. Dr. Callan's pentobarbital opinions are based on his extensive relevant qualifications, reliable methodology, and proper analysis of reliable evidence from CPF and the U.S. Food and Drug Administration ("FDA").

First, Dr. Callan's opinions are supported by his extensive qualifications. Dr. Callan specializes in "statistics, research methodology, toxicology, and biochemistry." (Ex. 1 ¶1.)[3] He has a doctorate in psychology and has researched published seven peer-reviewed articles on topics such as lead and cadmium contamination in infant formulates and the effects of exposure to various toxic substances. (*Id*. at Curriculum Vitae ("CV") p. 1, 2.) Dr. Callan is a sought-after speaker on the subject of toxin exposures and has "lectured on the topics of analytical design and data analysis." (*Id*. ¶4, CV p. 3-4). He also teaches graduate level statistics courses and introductory biopsychology and psychopharmacology courses. (*Id*. at CV p. 6-7.) Perhaps most significantly, Dr. Callan is also currently a Senior Vice President and past director of Research and Development of Ellipse Analytics, an analytical chemistry lab that tests samples of food and other consumer goods for industrial contaminants and environmental toxins, and he has previously worked with a company to undertake a risk assessment regarding contamination of raw materials getting into a finished product. (Ex. 1 ¶4, CV p. 1-10.) These qualifications and expertise in the actual area he is testifying about reflects a significant part of his life's work. *See Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995) ("*Daubert II*") ("One very significant fact to be considered is whether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying.").

Second, the opinions contained in Dr. Callan's expert report are based on his thorough review of transcripts of depositions taken in this matter, of relevant documents produced by CPF, of the Plaintiffs' Third Amended Class Action Complaint, and of relevant FDA reports and other

[3] The report attached to CPF's memorandum sets forth Dr. Callan's opinions related to BPA found in its Dog Food. However, CPF's motion challenges Dr. Callan's related to pentobarbital. Plaintiffs attach that pentobarbital-related report to the Declaration of Rebecca A. Peterson as Exhibit 1.

documents related to the undisputed pentobarbital contamination of CPF's Dog Food. (*Id*. ¶5.) Dr. Callan's review and analysis of evidence included CPF records that showed JBS USA Holdings, Inc. (a subsidiary of JBS S.A.) and its rendering facility MOPAC located in Eastern Pennsylvania (collectively, "JBS") supplied at least two lots of tallow that were in fact contaminated with pentobarbital and later used in the production of CPF Dog Food. (Dkt. 127-3 at 8:11-14, 8:23-9:3.) The pentobarbital-related evidence that Dr. Callan carefully and thoroughly analyzed, is undeniably reliable, and his pentobarbital opinions based on such reliable evidence, are informed by sound methodologies.

More specifically, the relevant documents that Dr. Callan examined, included documents supporting the fact that pentobarbital was indeed present in two lots of tallow shipped to CPF. For example, Dr. Callan reviewed documents related to FDA pentobarbital testing from 2002, the FDA's Establishment Inspection Report at CPF, as well as relevant correspondence between CPF and the FDA. Dr. Callan's expert opinion includes that the pentobarbital that was allowed to contaminate the Dog Food would not be eliminated by the manufacturing process of the dog food. (Ex. 1 ¶¶5, 6(b)-(d).) In other words, once the pentobarbital was introduced through the ingredients used to manufacture the food, some level or amount of pentobarbital would ultimately remain in the finished kibble. *Id.* Dr. Callan testified:

> In the previous parts of the report, we discuss how pentobarbital was present in a raw material made by JBS, purchased by Champion. That raw material was, in turn, used to create a finished product. We know from the work the FDA has done that raw material—the pentobarbital contained within that raw material is not destroyed in entirety during the manufacturing process. So the logic there is it is likely that Champion pet food, made with contaminated starting material, contains some amount of pentobarbital.

(Dkt. 127-3 at 70:18-25.)

Relying at least in part on information from CPF and the FDA, Dr. Callan concluded that pentobarbital was introduced into CPF Dog Food via the contaminated beef tallow; and that some,

if not all, of the pentobarbital then survived the manufacturing process; and that the corresponding CPF Dog Food contained some level of pentobarbital. (Ex. 1 at ¶6(d).) Dr. Callan testified as such:

> Q. When you say "some level," what do you mean?
>
> A. I go into more detail later in the report on this, which I presume we're going to go to at some point here. But because pentobarbital is present in one of the ingredients and because pentobarbital is not destroyed during the manufacturing process and because that ingredient is being included in the finished product, some amount of that pentobarbital will persist in the finished good.

(Dkt. 127-3 at 12:25-13:1-12.)

CPF argues that Dr. Callan's opinion that CPF's Dog Food contains some level of pentobarbital is "baseless" because he fails to criticize or replicate Texas A&M's testing. (Dkt. 127 at 3-7.) However, as Dr. Callan's report and testimony reflect, his opinions and the findings of Texas A&M are not mutually exclusive:

> The proper conclusion in the event of a "non-detect" is to conclude just that – that the testing chemist (here Texas A&M laboratory) was unable to detect the analyte. This does *not* mean the analyst is asserting that the analyte was not present at some level. As such, the non-detect findings of the Texas A&M laboratory do not contradict [Dr. Callan's] logic.

(Ex. 1 ¶6(d)(i).) Dr. Callan's opinion is that the small sample of CPF Dog Food tested contains some level of pentobarbital, which includes amounts below 2 parts per billion ("ppb"). (*Id*. ¶6(d).) Dr. Callan specifically testified to this point:

> Q: And that logical explanation, I take it, is that the pentobarbital in the ingredient, incoming ingredient, beef tallow, was diluted to such an extent that if it's present at all, it's below 2 parts per billion?
>
> A: That is the argument, yes.

(Dkt. 127-3 at 71:14-19.)

CPF's own purported expert, Dr. Robert Poppenga, reached the same conclusion, confirming that a "non-detect" finding at Texas A&M does not preclude the possibility that the

small sample of CPF Dog Food tested for pentobarbital could contain pentobarbital below 2 ppb. His specific deposition testimony on this point is as follows:

> Q: And so let's say of those 11 samples that were tested by Texas A&M, if they contain 1.5 parts per billion of pentobarbital, would Texas A&M's testing pick that up?
>
> A: No. Their reporting limit, their limit of detection, was two parts per billion.
>
> Q: And same if one of them had 1.75 parts per billion?
>
> A: Correct.
>
> Q: And 1.9 parts per billion?
>
> A: In theory, no, because it's two parts per billion or greater.

(Ex. 2, Dep. of Dr. Robert Poppenga, August 26, 2019, at 29:8-19).

Dr. Callan's underlying calculations and resulting opinions with regard to the pentobarbital will be helpful for a jury to understand that some amount of pentobarbital was present in the CPF Dog Food at-issue, despite Texas A&M's "non-detect" testing result, which only precludes the possibility that the few samples tested did not have pentobarbital in excess of 2 ppb. Dr. Callan's helpful opinions are based on a methodical and careful analysis of relevant and reliable authoritative documents, following the information and data obtained from the evidence in a step-by-step process, to reach his opinions. Dr. Callan's expert report indeed reveals sound methodology applied to the facts of this case to reach sound, reliable, and helpful expert opinions. The Seventh Circuit expressly states, "Where an expert's hypothetical explanation of the possible or probable causes of an event would aid the jury in its deliberations, that testimony satisfies *Daubert*'s relevancy requirement." *Smith*, 215 F.3d at 718-19; *see also NutraSweet Co. v. X-L Eng'g Co.*, 227 F.3d 776, 789 (7th Cir. 2000) (permitting expert to testify to inferences based on someone else's test results and his own experience). In particular, Dr. Callan's opinion that CPF's

Dog Food "would contain some amount of pentobarbital" is likewise permissible. It is for the jury to decide the weight to be accorded such an opinion based on probability. *Smith*, 215 F.3d at 719.

CPF also argues for exclusion of Dr. Callan's expert opinions because Dr. Callan only observed, but did not do, the testing leading to his opinions. (Dkt. 127 at 5-6.) However, Dr. Callan is not required to conduct his own testing and instead can rely upon sufficient and reliable data to come to his opinion which, as discussed above, is exactly what occurred. *See* Fed. R. Evid. 703 ("An expert may base an opinion on facts or data in the case that the expert has been made aware of ***or*** personally observed."). As in *NutraSweet*, CPF "does not challenge the underlying data." 227 F.3d at 789. And "an expert is not always required to personally perceive the subject of his analysis." *Id*. at 790. Dr. Callan's expert opinions are based on reliable information, such as information from the FDA, the Texas A&M lab, and testimony from JBS employees, among other evidence. It "was verifiable, and Dr. [Callan] used reliable methodologies in reaching his opinion." *Id*. Those opinions should not, therefore, be excluded. *Id*.

Moreover, despite CPF's suggestions to the contrary, Dr. Callan's testimony that he understands that the FDA considers a product with "detectable" levels of pentobarbital to be adulterated is not a concession that the Dog Food is unadulterated. (Dkt. 127-3 at 103:18-104:21.) CPF misconstrues Plaintiffs' allegations, which rest solely on whether ***any*** amount of pentobarbital was present in CPF Dog Food. CPF does not dispute Dr. Callan's correct opinion that "the failure to detect pentobarbital in the finished product is the result of serial dilution of the pentobarbital as raw materials are blended into finished goods, not the absence of the compound in the finished product." (Ex. 1 ¶6(d).) In other words, "non-detection" of pentobarbital does not mean a categorical conclusion that no pentobarbital is present. As mentioned above, CPF's own expert

witness, Dr. Poppenga, confirms that "non-detect" does not exclude this possibility. (Ex. 2 at 29:8-19.) Dr. Callan further elucidates this point as follows:

> [A] more plausible conclusion in line with all available information is that the pentobarbital present in the JBS raw material has been diluted below the ability of Texas A&M to detect rather than eliminated during processing. Indeed, based on Champion's own estimations (provided by Exponent), the inclusion rate for beef tallow in Champion products ranged from 2.89% to 6.07%. This means that a 16 ppb pentobarbital hit (the low point of the two lots of tallow we know Champion purchased from JBS) in tallow would be diluted down to below 1ppb in the finished kibble (0.46ppb) – below the stated LODs of the laboratories performing the testing. This would give the false impression of an "all clear" when in fact the pentobarbital had only been diluted below detection or as discussed below was contained in other parts of the kibble not tested.

(Ex. 1 ¶6(d)(i).) Thus, as Dr. Callan explains, CPF Dog Food likely contains some level of pentobarbital.

Dr. Callan's opinions are helpful for the fact finder as the presence of ***any*** amount of pentobarbital in CPF Dog Food is probative of the pentobarbital contamination allegations levied against CPF. CPF's argument is devoid of any acknowledgement, mention, or reference that pentobarbital can present below a concentration of 2 ppb. While CPF would like to pigeonhole the issue of pentobarbital to this arbitrary threshold, Dr. Callan's expert opinions are helpful for the jury to understand that pentobarbital can be present even when not "detected" by some limited laboratory testing. As Dr. Callan's expert opinions would be helpful to a jury, are based on reliable information, sound methodologies, and supported by his expert qualifications, the Court should deny CPF's motion to exclude Dr. Callan's expert opinions regarding pentobarbital.

B. Dr. Callan's Opinions that CPF's Sampling Was "Insufficient to Assess the Actual Risk" Is Based on Dr. Callan's Experience and Expertise and Relies on Sufficient Facts and Data

Dr. Callan is highly qualified to render opinions regarding data sampling and analytics. His expertise includes his background in teaching statistics and research design courses at the both the undergraduate and graduate levels, his prior experience lecturing on these topics, and his day-to-

day work at Ellipse Analytics, where Dr. Callan serves as a Senior Vice President. (Ex. 1 ¶4, CV 1-10. While CPF claims Dr. Callan has no basis for rendering an opinion, in fact, Dr. Callan has direct experience with determining adequate sample sizes for contaminant testing:

> Q: Okay. Have you ever done statistical analyses to determine what would be a statistically representative sampling for detecting a toxin in the processing of food?
>
> A: Yes.
>
> Q: Tell me about that.
>
> *[Omitted discussion regarding NDA from prior work]*
>
> A: Okay. We did some work with a company around the presence of a—of a contaminant of concern, and, you know, it started by identifying the root case, the—the antecedent material, and then it went into raw material testing to determine the prevalence and frequency. And from there, we developed a plan to perform stratified testing in order to guarantee that the product wasn't present. So the analysis there relied upon knowing several factors. You have to know the frequency with which the contaminant shows up, the concentration with which the contaminant shows up, and the inclusion rate in the finished product, and that helps you then go in and determine, in order to make sure that your product, to a reasonable degree of scientific certainty, is going to be consistently clean, in addition to testing the raw material, which is the key. You have to test the raw material. You can then perform a statistically meaningful and representative sampling of the good as a secondary control.

(Dkt. 127-3 at 31:6-32:11.)

Disregarding these qualifications, CPF argues that Dr. Callan "has no basis for opining that CPF's pentobarbital sampling was insufficient," and as such should be excluded. (Dkt. 127 at 7.) This is false, and this Court should give due weight to Dr. Callan's qualifications when deciding CPF's Motion. *Smith*, 215 F.3d at 718.

To support its arguments, CPF cherry-picks deposition testimony to give the appearance that Dr. Callan did not know the pertinent details of CPF sampling for pentobarbital. (Dkt. 127 at 7-9.) However, in fact, Dr. Callan testified that he understood that the CPF sampling process included taking retained samples from storage and using them for testing. (Dkt. 127-3 at 17:5-15.)

He also testified that these retained samples were pulled from various points in CPF's production runs. (*Id.*) CPF nitpicks at Dr. Callan's testimony, focusing on the fact that he did not personally observe the collection of samples and does not know the details of CPF operational procedures (i.e. how long CPF takes to produce a lot of finished Dog Food), while ignoring his familiarity with the sample size of less than one pound. (*Id.* at 19:7-22.) Given his extensive background and his review of CPF's testing protocol, Dr. Callan is well qualified and well informed to criticize CPF for improperly extrapolating such a small size from 1.7 million pounds of finished Dog Food.

CPF's assertion that Dr. Callan did not quantify parameters for sufficient testing is likewise unfounded and unsupported by Dr. Callan's testimony. (Dkt. 127 at 9-11.) Dr. Callan opined that CPF's sampling size had a margin of error of 20%. (Ex. 1 ¶6(d)(ii).) Dr. Callan's explained further at his deposition:

> Q: Then you talk here about "Testing such a small amount creates a massive 20% margin of error." …How did you calculate this 20 percent margin of error?
>
> A: Margin of error calculation, in this instance, is a good proxy for variability. So … it's a standard formula that you can use in statistics, if you know the total population size, you know the confidence interval that you want to attain, and you know the amount … of the sample. I mean, it's … just a straight math formula that tells you it's not."
>
> Q: What are you relying on for that opinion about 20 percent margin of error?
>
> A: I just said. I know how much kibble there was. I know how much sample they did. I know the confidence interval you want. And then math tells me the margin of error.

(Dkt. 127-3 at 79:12-80:5.) Dr. Callan continues, explaining:

> A: What that says is, if the goal is to simulate what's actually going on at the population level, here population being defined as the 1.7 million pounds of available … kibble, that testing 0.26 [pounds of kibble] would result in such a wide degree of error around the true value that it would be difficult to accurately estimate whether you were seeing something real or not."

(*Id.* at 82:2-9.)

Dr. Callan further opines on what a sufficient sample size for adequate pentobarbital testing of the Dog Food would be:

> Q: That was my next question. What would be an acceptable margin of error under these circumstances?
>
> A: It depends how certain they want to be that they know how much pentobarbital is present in a product. Typically;… in my own personal experience, when conducting analytics, whether it's analytics of … consumer or human behavior or analytics in this sense, I typically shoot for under 5 percent error.
>
> Q: And that's what you do in the ordinary course of business at Ellipse Analytics?
>
> A: Yeah. Which is to say I want to be 95 percent sure that the true value is within plus or minus 5 percent of what I'm seeing, not plus or minus 20.

(Id. at 83:9-24.) Dr. Callan adds:

> Q: Okay. So what should Champion have done?
>
> A: They should have tested a larger amount of sample. And in terms of how much sample, I would have to perform a statistical analysis in order to determine how much.

(*Id.* at 26:13-17.)

This testimony shows a reality that is much different than the version CPF wants this Court to believe. Dr. Callan's expert report does not attempt to, as CPF argues, "rebut something with nothing." (Dkt. 127 at 11.) Dr. Callan's opinions on the insufficiency of CPF's sampling is based on CPF's miniscule sample size taken from the 1.7 million pounds of kibble. (Ex. 1 ¶6(d)(ii).) Dr. Callan expands on this point, noting that such a small sample would create a massive 20 percent margin of error, which is quadruple the margin of error that Dr. Callan would expect to see in an empirically sound and sufficient sample. (*Id.*; Dkt. 127-3 at 83:9-24.) Dr. Callan's suggestion for sufficient testing is straightforward—test more kibble until a 5 percent margin of error is achieved. (Dkt. 127-3 at 83:9-24.) While Dr. Callan did not opine on the specific amounts of kibble associated with his recommended margin of error, Dr. Callan need not do so to establish that CPF's

testing was inadequate. Dr. Callan has more than a sufficient basis to opine that CPF's pentobarbital sampling was lacking.

To the extent that CPF disagrees with the factual bases that underpin Dr. Callan's opinion, it may voice its criticisms through cross-examination and its own expert testimony at trial. CPFs' criticisms go towards weight, not admissibility. *United States v. 17.69 Acres of Land*, 2004 WL 5632928, at *3 (S.D. Cal. Dec. 20, 2004) ("Rather than excluding expert testimony because of the facts and data upon which it relies, 'it is up to the opposing party to examine the factual basis for the opinions in rigorous cross-examination.'"). As Dr. Callan's opinions are based on reliable information, sound methodologies, and his expert qualifications, the Court should not exclude his opinions, which would be helpful to the jury when weighing the evidence presented in this case. *i4i Ltd. P'ship*, 598 F.3d 831, 852 (Fed. Cir. 2010), *aff'd* 131 S. Ct. 2238 (2011) ("When the methodology is sound, and the evidence relied upon sufficiently related to the case at hand, disputes about the degree of relevance or accuracy (above this minimum threshold) may go to the testimony's weight, but not its admissibility.").

C. Dr. Callan's Opinions that the Heterogeneous Nature of Pentobarbital Requires Larger Sample Size for Testing Is Based On Reliable Information, Methodologies, and Expertise

Dr. Callan's opinions on the heterogeneous nature of beef tallow and the resulting heterogeneous distribution of pentobarbital in the Dog Food is based on reliable information, methodologies, and expertise. In coming to his conclusions, Dr. Callan based his understanding and review on relevant testing data provided from reputable analytical laboratories and documentation from CPF and the FDA. (Ex. 1 ¶¶5, 6(a).)

First, Dr. Callan reviewed documents obtained from the Pennsylvania Department of Agriculture via a Freedom of Information Act ("FOIA") request "show[ing] a sample of tallow produced by JBS contained 47 [] ppb of pentobarbital;" another set of tallow tests by UC Davis

"show[ing] traces of pentobarbital from 16 to 240 ppb, of which two…were sent to [CPF];" and additional correspondence between JBS and the Pennsylvania Department of Agriculture "detail[ing] at least two instances of JBS tallow…containing between 620 and 680 ppb of pentobarbital." (*Id*.) Based on such reliable data, Dr. Callan concludes not only that pentobarbital was present in multiple lots of JBS tallow, including that purchased by JBS, but also that the wide variance in pentobarbital contamination, in his expert opinion, is indicative of the fact that "[t]he amount of pentobarbital varied widely from sample to sample." (*Id*.) Simply put, "[q]uantification of these results revealed a highly heterogenous concentration of pentobarbital lot to lot, with results ranging from what UC Davis calls 'trace' hits (single digit part-per-billion) to 640 parts per billion or more." (*Id*.)

Furthermore, Dr. Callan testified that he had previously reviewed the FDA's updated methodology for testing of pentobarbital in pet food, which specifically requires that pentobarbital is tested from a homogenized sample of beef tallow. (Dkt. 127-3 at 92:5-25.) That guidance provides that, "if the sample does not appear homogeneous, which is to say if sample appears heterogeneous, stir the 25 grams manually with a spatula or a spoon to ensure homogeneity." (*Id.* at 93:1-4.) The FDA's warning against the use of heterogeneous samples of beef tallow when testing for pentobarbital supports Dr. Callan's concern over the impact of testing heterogeneous beef tallow samples for pentobarbital is neither speculative nor baseless.

Based on this reliable information, Dr. Callan opines that heterogeneity of beef tallow is a significant and relevant consideration because an uneven distribution of pentobarbital would further frustrate the ability to accurately estimate pentobarbital through sample testing of the Dog Food. (*Id.* at 21:23-22:13.) Specifically, Dr. Callan testified that representative testing using composite samples is not ideal for heterogeneous contaminants because mixing of multiple

samples would "run the risk of even further diluting your sample and missing what was there." (*Id.* at 22:9-13.) With this in mind, Dr. Callan concludes that the heterogeneous nature of pentobarbital distribution in the Dog Food necessitates a larger sample size to accurately estimate the pentobarbital contamination in CPF Dog Food. (*Id.* at 19:14-19.)

CPF criticizes Dr. Callan for not being familiar with certain granular details such as how JBS's tallow is transported to CPF, how the tallow is stored, the temperature at which it is stored, how it is transported from the facilities to the truck and then to the next facilities. Dkt. 127. at 12-14. However, CPF offers no substantive evidence that these details are relevant when determining whether an ingredient is homogenous or heterogeneous. CPF's argues that Dr. Callan did no personal testing of the lots is likewise unavailing because Dr. Callan may base his opinions on what he has been made aware of, as he has done here. Fed. R. Evid. 703; *NutraSweet*, 227 F.3d at 789.

IV. CONCLUSION

For all of the foregoing reasons, Plaintiffs respectfully request this Court deny CPF's requests to exclude Dr. Callan's pentobarbital-related opinions and all testimony related to those opinions.

Dated: June 10, 2021

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 10th day of June, 2021, I served the foregoing document on all counsel of record via the Court's electronic delivery system.

s/ Rebecca A. Peterson
Rebecca A. Peterson